CMS CLIA UPDATE for CLIAC

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CMS CLIA UPDATE

- **ITEMS FOR DISCUSSION**
  - Current laboratory enrollment
  - Final Quality System Regulations published
  - Corresponding Surveyor Interpretive Guidelines
  - Surveyor training
  - POL Brochures
  - Status of genetic testing NPRM

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CURRENT CLIA ENROLLMENT

	TOTAL LABS	POLs
	180,000	101,000
LABS BY CERTIFICATE TYPE		
Compliance (CMS Surveys)	21,027	13,873
Waiver	98,193	47,226
PPM	38,321	31,977
Accredited	16,171	6,294

EXEMPT	NY-exc. POLs	WA
	2841	2741

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- Final CLIA Quality System Regulations published Jan. 23, 2003!!
- Ten years in the making—but who's counting??

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- **HIGHLIGHTS OF FINAL CLIA REGS**
  - Ends moderate complexity QC phase-in.
  - Defines new terms.
  - Reorganizes standards to parallel lab workflow.
  - Grandfathers Ph.D. existing hi complexity lab directors; requires board cert. for NEW dirs.
  - Eliminates FDA QC role.
  - Includes local, state & federal law coordination.
  - Contains minimal changes; affects only moderate & high complexity laboratories.

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- Rationale for the Final CLIA Regulations
  - Respond to comments.
  - Incorporate CLIAC recommendations.
  - Recognize new & improved test technologies.
  - Utilize 10 years of CLIA data.
  - Close out phase-ins.
  - Include basic Quality System concepts.

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- **NEW TERMS**
  - Moderate & high complexity QC==**Nonwaived**
  - Quality Assurance==**Quality Assessment**
  - PT, QC, PTM, QA,personnel==**Quality System**
  - NIDA==**SAMHSA**

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- **SO WHAT'S NEW IN QC??**
  - – Reduces hematology & microbiology QC requirements.
  - – Creates options for a default of external QC or "equivalent" QC as defined by CMS.
  - -- Reduces number of specific specialty QC requirements.
  - --Includes test method verification for NEW mod. complexity tests.
  - --Closes moderate complexity QC phase-ins.— Eliminates FDA role in CLIA QC.

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- **WHAT ELSE IS NEW??**
  - Created two new Subparts from three:
    - » Subpart J—Facility Administration
    - » Subpart K—Quality System

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- **Subpart J—Facility Administration**
  - Facilities
  - Transfusion
  - Record retention
  - Safety

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- **Subpart K—Quality System**
  - Mirrors the flow of a specimen through the lab; starting with those that are generally applicable.
  - Calibration & cal. verification.
  - Establishment & verification of test method.
  - Reagent storage.
  - Specialty & subspecialty requirements.

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- Info to Facilitate Compliance with Final Regulations
  - Surveyor Guidelines on CMS website end 2003.
  - Surveyor training completed end of Sept.
  - POL " Brochures" end 2003.
  - One 2-year cycle of "educational" inspections w/ no enforcement unless risk to patient safety.

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- **Status of Genetic Testing NPRM**
  - NOI published by CDC 2001.
  - Comments received & reviewed.
  - NPRM drafted w/ remaining issues to solicit comments.
  - Regulation on CMS regulation publication schedule presently.

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THE END!!

THANK YOU!!!

QUESTIONS??